# Exhibit A

# Stephen M. Factor, MD, FCAP, FACC

PROFESSOR OF PATHOLOGY & MEDICINE 19 Dan Beard Lane Redding, CT 06896

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October 9, 2012

Nils B. (Burt) Snell, Esq. Butler, Snow, O'Mara Stevens & Cannada, PLLC Suite 400 500 Office Center Drive Fort Washington, PA 19034

Re: Linda Gross

Dear Mr. Snell

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I am the Chairman of the Department of Pathology at Jacobi Medical Center. I am licensed to practice medicine in the State of New York and I am also a Licensed Laboratory Director by the State of New York. I am certified by the American Board of Pathology in anatomic and clinical pathology. I have academic appointments in the Department of Pathology and the Department of Medicine (Division of Cardiology) at the Albert Einstein College of Medicine, Bronx, N.Y., where I serve as a fully tenured professor. I am a Fellow of the College of American Pathology and the American College of Cardiology. Additional information regarding my training, employment history, qualifications and publications are detailed in my curriculum vitae, which is attached.

I have reviewed pathological materials as set forth below and also attached is a list of materials that I have reviewed in this matter. The following is a description and analysis of the pathological materials pertaining to Mrs. Linda Gross and my opinions in this matter.

**Linda Gross Pathology Materials:** 

NMHC (5/22/07), N07-7921 Rectovaginal mass (slide marked with ink dots)

Fibrous stroma, focally with vaginal mucosa. Multiple empty spaces consistent with mesh fibers. Virtually no inflammatory reaction (very mild focal lymphocytic inflammation) in areas of mesh. Focal hemosiderin (consistent with prior hemorrhage). Multiple lakes of foamy and proteinaceous exudate. Focal vessels with fibromuscular

sclerosis. Some residual fibers are refractile and bi-refringent (dots around vessels and nerves).

Mayo Clinic (10/07), CR07-8397 Left posterior vagina (A1-2); Right posterior vagina (B1); (tissues with ink dots)

Fibrous and focal adipose tissue with focal mesh fiber spaces; some residual refractile material. Variable inflammation with some fibers showing no significant inflammatory reaction, and focally other groups of fibers with lymphocytic and multinucleated giant cell (MNGC) reaction. Multiple nerve fibers and occasional ganglia in fibrous tissue; hemosiderin pigment (dots around nerves and ganglia).

Mayo Clinic (1/08), CR08-678 Large bowel biopsy (A1-2); Upper posterior vagina (B1; mesh gross); ischial spine (C1; mesh gross)

A1-2: Large bowel biopsy: fat with remote necrosis (no intestine)

B1: Upper posterior vagina: Fibrous stroma; fibromuscular vascular sclerosis; blood vessel (vein) with remote thrombosis and hemosiderin; stroma with insignificant inflammation; multiple nerves and ganglia in fibrous tissue (vessels are not damaged or collapsed – they are sclerotic with focal lumen stenosis, not associated with ischemia). C1: Ischial spine mesh: Mesh was gross only. Fibroadipose tissue in fibrous stroma with hemosiderin pigment and lymphocytic inflammation. Several granulomata (most likely foreign-body-type). Multiple nerve fibers with focal degeneration (one nerve bundle with changes consistent with neuroma). One vessel with hyalinization and multiple MNGC. Dots around nerves and hemosiderin.

SJHMC 6/09, S09-3382 Left ischial spine

Fragments of bone and fibrous tissue (periosteum) with focal calcification.

SJHMC 9/09, S09-5269 Soft tissue left buttock

Multiple fragments of fibrous tissue with focal purulent inflammation and granulation tissue consistent with abscess

SJHMC 10/09, S09-6422 Left buttock

1A, 2A: Fibrous and focal skeletal muscle tissue with chronic inflammation and maturing granulation tissue; granulation tissue is consistent with wall of fistula tract.

1B: Fibroadipose and skeletal muscle tissue with adjacent fibrous stroma, chronic inflammation, focal suture material with inflammation, and cautery (thermal) artifact. Dot of hemorrhagic fibrous stroma.

# SJHMC 3/11, S11-1706 1A-C Fallopian tubes

Fallopian tubes with small leiomyoma in paratubal tissue of one tube.

# SJHMC 6/16/11, S11-3922 1A, 3A, 4A-B Mesh and retropubic mass

1A: Retropubic mass: small fragment of cauterized blood vessel.2A: Mesh fiber: Grossly described as 2 strands of hair-like material

3A: Luteinized ovarian cyst.

4A-B: Small fragments of ovary with corpora albicans and follicular cysts

# **Defense Slides:**

N07-7921 (1 re-cut and 1 blank): similar to Plaintiff's slide

**S01-1009** (3 re-cuts and 3 blanks)

A1: Cervix and endocervix; stroma with multiple sclerotic blood vessels

B1: Endomyometrium with weakly proliferative endometrium and chronic endometritis

C1: Endomyometrium with disordered weakly proliferative endometrium with chronic endometritis

S03-878 (1 re-cut and 1 blank)

Gallbladder with chronic cholecystitis

S10-1768 (1 re-cut and 1 blank)

Anal hemorrhoids

Mayo Clinic S07-8397 Left A1-2; Right B1

A1-2: Many nerves in fat and normal stroma without surrounding scar tissue. Smaller branches of nerves associated with fibrous tissue secondary to fat necrosis. Largest myelinated nerve is in fat and stroma. Most nerve fibers have no or minimal inflammation. Many blood vessels including artery are sclerotic with intimal/medial fibromuscular hypertrophy and hyperplasia; some in scar tissue, others in fat and stroma.

**B1:** Large sinuous nerve/ganglion in fibrous tissue associated with fat that has undergone fibrosis (likely due to fat necrosis). No mesh fibers are adjacent. Scar tissue with hemosiderin associated with entrapment of nerve. Mesh fibers at edge of tissue with surrounding fibrous tissue and minimal to no inflammation.

#### **Conclusions:**

The tissue response to PROLIFT Ethicon Mesh is not unusual or unique. It is similar to the response secondary to implantation of all foreign materials used for tissue support including sutures (mono- and polyfilament), Dacron, PTFE, and bio-materials that I have studied. Foreign bodies, and specifically mesh of all types and pore size, elicit fibrosis with ingrowth of type I collagen between the mesh pores in order to incorporate the mesh into the tissue for biological support(and in the case of vascular grafts, to prevent blood vessel leakage). Fibrosis, regardless of whether it is secondary to traumatic or iatrogenic injury, or a response to tissue necrosis or damage, elicits a chronic inflammatory response in association with the maturation of the collagen fibers. The development of collagen, including that secondary to the use of mesh, leads initially to granulation tissue (capillaries and fibroblasts, with deposition of pro-collagen, immature collagen (type III), and finally mature type I collagen over time. This process of collagen being secreted by fibroblasts and maturing is always associated with inflammation. During the granulation tissue phase there are PMNs and mononuclear cells; as granulation tissue evolves into fibrosis and neo-vasculature, the inflammatory component consists of mononuclear cells (lymphocytes, monocytes, plasma cells, and variable eosinophils). If the fibrosis develops in response to a foreign body, including mesh implantation, then the inflammatory response includes reactive macrophages, and MNGC (with both derived from monocytes). If foreign bodies are present, the inflammatory response is chronic and persistent. It is also important, when evaluating tissue fibrosis and inflammation associated with foreign material, to recognize that patient responses are variable and unpredictable. For unknown reasons, some patients may have a much more intense response than others, even when using similar materials and surgical techniques.

Surgery, per se, regardless of whether foreign material is used (including sutures) will lead to tissue damage with necrosis of connective tissue and fat. There is always some degree of associated damage to blood vessels, and tissue nerve bundles, leading to entrapment. These responses also are not unique to mesh. Ms. Gross had abundant evidence of prior fat necrosis with fibrous tissue replacement of fat, and multiple areas of hemosiderin-pigment deposition due to the breakdown of red blood cells secondary to surgical hemorrhage. These changes are induced by surgery, and have nothing to due with mesh. They were present in areas of tissue sampling in which mesh fibers were not present.

In both N07-7921 and CR07-8397, there was variable inflammation ranging from none to mild lymphocytic, to areas with lymphocytes and MNGC. This hardly reaches the level of "...a severe degree of chronic inflammation that has resulted in the deposition of dense fibrous scar tissue, in addition to damaging blood vessels and nerves." Any scar tissue following surgery potentially can damage blood vessels and entrap nerves, whether mesh is used or not. There is no objective scientific evidence that blood vessels were affected and/or damaged by mesh emplacement. In fact, in S01-1009 (uterus and cervix), well before mesh was employed, Ms. Gross had evidence of blood vessels in her cervix with fibromuscular hypertrophy and hyperplasia (vascular sclerosis), including changes

similar to those identified by Dr. Welch on slides marked with dots. The sclerotic vessels in the cervix also occurred without any surgery, indicative of common findings in women's gynecologic tracts. Ms. Gross also had evidence of chronic endometritis in the uterus in this specimen, possibly indicating that she had or was susceptible to chronic inflammation in her pelvic organs. Furthermore, although there was no biopsy, she was described as having hemorrhagic and interstitial cystitis 5 years later.

Dr. Welch makes much of the entrapment of nerves, and ascribes it to the mesh. As noted, any time there is surgical manipulation of tissue, there is a potential for scar formation, and nerve entrapment or direct damage to nerves. Only one nerve in all of these specimens had changes consistent with a neuroma, most likely secondary to surgical trauma. However, this neuroma was in tissue C08-678 C1, which did not have mesh in the adjacent stroma. Entrapment of nerves can occur due to fibrous tissue developing following fat necrosis, tissue hemorrhage, and surgical incisions, all of which were present or had occurred in Ms. Gross. There is also absolutely no way to ascribe subjective symptoms of pain to particular nerves surrounded by fibrous tissue. Pain can be associated with a neuroma (of which there was only one), and may occur with inflammation of the neural tissue (which was not observed). Similarly, sclerotic changes of blood vessels are not equivalent to ischemia, for which there was no evidence in her tissues. There are abundant blood vessels in vaginal and pelvic tissues, and sclerosis of some vessels does not necessarily lead to tissue ischemia.

As a final point, the abscess and buttock fistula that Ms. Gross developed is absolutely not unique to the mesh used in her repair. Any foreign material, any obstruction to normal drainage, surgical and non-surgical trauma, and infections, can all lead to fistula formation.

In conclusion, in my opinion, within a reasonable degree of medical certainty, Ms. Gross had an unremarkable response to the Ethicon mesh. The inflammatory changes were not significant, and they were highly variable. She had scar tissue characteristic of what would be expected after multiple surgical procedures. Similarly, her tissues had evidence of fat necrosis and hemorrhage that independently led to further scarring, often in areas distant from mesh fibers. The entrapment of some nerves, and the sclerosis of blood vessels was a result of surgical manipulation of the tissues, and cannot be linked to speculative and biologically unsupported effects of the mesh. At least some of the vascular sclerosis may be a reflection of underlying changes in blood vessels having nothing to do with mesh, or surgery.

All of the opinions expressed in this report have been stated within a reasonable degree of medical certainty. I reserve the right to supplement my opinions and respond to the testimony of Dr. Welch. I may also provide additional testimony in response to testimony of plaintiff's experts on subjects which are within the scope of my professional expertise.

Sincerely,

Stephen M. Factor, M.D.
Professor of Pathology & Medicine
Albert Einstein College of Medicine
Chairman, Department of Pathology Jacobi Medical Center

# LIST OF MATERIALS – LINDA GROSS

# I. PATHOLOGY / MEDICAL RECORDS / OTHER RECORDS

Pathology slides in the Gross case

Disc containing pictures of pathology slides for Gross case

Operative and Pathology Reports for Gross

Linda Gross

Avera McKennan Hospital, 1-122 (medical records), 1-3 (billing)

Bridgeway Counseling Center, 2-9

Brown Clinic, 1-760

Clary Document Management, 1-24

Innovative Pain and Procedural Center, 1-47

Lake Area Vo Tech, 1-3

Lutheran Social Services, 1-46

Mayo Clinic, 1-428

Medicare and Medicaid, 1-50

Medical Advanced Pain Specialists, 1

North Memorial Medical Center, 1-42 (medical records), 1-4 (billing)

Prairie Lakes Hospital Path Slides

Prairie Lakes Hospital Path Reports 1-9

Prairie Lakes Hospital, 1-530 (medical records), 1-182 (billing)

Sanford Clinic Urogynecology, 1-18

Sanford Clinic Watertown, 1-54

Sanford Health Network, 1-2

SSA Records, 1-1368

St. Joseph, 1-592 (medical records), 1-54 (billing)

St. Joseph Advanced Pelvis Surgery, 1-80

Exhibit 7 to Linda Gross's 10.12.10 Deposition, Benson medical records

Medical records provided by plaintiff

VNR, 1-3

Linda Gross Complaint and Plaintiff Fact Sheet

# II. <u>DEPOSITIONS AND EXHIBITS</u>

Pamela Wicker, 4.2.12

Pamela Wicker, 4.3.12

Richard Bercik, 3.22.12

William Wicker, 4.3.12

Kevin Benson, 4.9.12

Bradley Gross, 6.6.12

Jeffrey Gross, 10.14.10

Linda Gross, 10.12.10

Linda Gross, 10.13.10

Linda Gross, 4.10.12

Terry Gross, 6.6.12 Tyler Gross, 6.6.12 Mary Johnson, 6.8.12 Jacalynn Lake, 6.8.12 Clark Likness, 6.7.12 Emanual Trabuco, 6.28.12 Edwin Gerrish, 7.30.12 Julie Gollnick, 7.31.12 Karen Holscher, 7.31.12 Alan Lawrence, 7.30.12 Patrick Retterath, 7.30.12

# III.ARTICLES/OTHER

Abdel-fattah, et al (2008) Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapsed

Abed, et al. (2011) Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapsed repair with graft materials: a systematic review

Afonso, et al. (2007) Mechanical properties of polypropylene mesh used in pelvic floor repair

Altman, et al. (2007) Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair

Altman, Daniel (2009) Sexual Dysfunctino after Trocar-Guided Transvaginal Mesh Repair of Pelvic Organ Prolapse

Altman, Daniel (2007) Short-term outcome after transvaginal mesh repair of pelvic organ prolapsed

Azevedo (2004) Understanding the Enzymatic Degradation of Biodegradable Polymers and Strategies to Control Their Degradation Rate

Bafghi, et al. (2005) Comparison between monofilament and multifilament polypropylene tapes in urinary incontinence

Barbolt (2006) - Biology of Polypropylene/Polyglactin 910 grafts

Binnebosel (2010) Impact of mesh positioning on foreign body reaction and collagenous ingrowth in a rabbit model of open incisional hernia repair

Binnebosel (2011) Biocompatibility of prosthetic meshes in abdominal surgery

Birch (2002) The role of synthetic and biological prostheses in reconstructive pelvic floor surgery

Blais (1976) The photo-oxidation of Polypropylene Monofilaments

Boukerrou (2007) Study of the biomechanical properties of synthetic mesh implanted in vivo

Boukerrou (2008) Tissue resistance of the tension-free procedure: What about healing?

Boulanger (2006) Tissue integration and tolerance to meshes used in gynecologic surgery: An experimental study

Boulanger (2008) Bacteriological Analysis of Meshes Removed for Complications after surgical management of urinary incontinence or pelvic organ prolapse

Boulanger (2008) Development of an animal model to study meshes used in genital prolapse surgery

Bracco, et al. (2005) Comparison of polypropylene and polyethylene terephthalate (Dacron) meshes for abdominal wall hernia repair: A chemical and porphological study

Bringman (2010) Hernia repair: the search for ideal meshes

Caquant, et al. (2008) Safety of Trans Vaginal Mesh procedure: Retrospective study of 684 patients

Clave, et al. (2009) Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants

Cobb (2005) The Argument for lightweight Polypropylene Mesh in Hernia Repair

Cobb (2006) Textile Analysis of Heavyweight, Mid-Weight and Light-Weight Polypropylene Mesh in a Porcine Ventral Hernia Model

Cobb, Heniford (2009) Mesh Terminology 101

Cosson (2003) Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal materials?

Cosson (2004) A biomechanical study of the strength of vaginal tissues Results on 16 postmenopausal patients presenting with genital prolapse

Cosson (2012) Biomechanical Properties of Human Pelvic Organs

Cosson, et al. (2005) Prolift (Mesh (Gynecare) for Pelvic Organ Prolapse Surgical Treatment Using the TVM Group Technique: A Retrospective Study of 687 Patients

Costello (2007) Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient

Costello, et al. (2007) Materials Characterization of Explanted Polypropylene Hernia Meshes

Cozad (2010) Material characterization of explanted polypropylene, polyethylene terephthalate, and expanded polytetraflouroethylene composites: Spectral and thermal analysis

Davila, et al. (2006) Clinical implications of the biology of grafts: conclusions of the 2005 IUGA Grafts Roundtable

Debodinance (1999) Tolerance of synthetic tissues in touch with vaginal scars review to the point of 287 cases

Deprest (2005) Synthetic and Biodegradable Prostheses in Pelvic Floor Surgery

Deprest (2006) The biology behind fascial defects and the use of implants in pelvic organ prolapse repair

Deprest (2007) Tensile Strength and Host Response towards Silk and Type I Polypropylene Implants Used for Augmentation of Fascial Repair in a Rat Model

Dietz (2003) Mechanical properties of urogynecologic implant materials

Dora, et al. (2004) Time Dependent Variations in Biomechanical Properties of Cadaveric Fascia, Porcine Dermis, Porcine Small Intestine Submucosa, Polypropylene Mesh and Autologous Fascia in the Rabbit Model: Implications for Sling Surgery

Dwyer (2006) Evolution of biological and synthetic grafts in reconstructive pelvic surgery

Elmer, Caroline (2009) Histological Inflammatory Response to Transvaginal Polypropylene Mesh for Pelvic Reconstructive Surgery

Elmer, Caroline (2009) Trocar-Guided Transvaginal Mesh Repair of Pelvic Organ Prolapse

Elmer, Caroline (2012) Risk Factors for Mesh Complications after Trocar Guided Transvaginal Mesh Kit Repair of Anterior Vaginal Wall Prolapse

Eth Doc (2012) PSE Study No. 08-0311 (Shrinkage)

FDA Reclass on PP Sutures

Iglesia, et al. (2010) Abstract Vaginal Mesh for Prolapse: A Randomized Controlled Trial

Jacquetin (2004) Conceptual Advances in the Surgical Management of Genital Prolapse

Jacquetin, et al. (2010) Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study

Jacquetin, et al. Abstract Prospective Clinical Assessment of the Trans Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse – One Year Results of 175 Patients

Julian (1996) The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall

Junge (2009) Adhesion formation of a polyvinylidenfluoride/polypropylene mesh for intraabdominal placement in a rodent animal model

Karlovsky, et al. (2005) Synthetic Biomaterials for Pelvic Floor Reconstruction

Klinge (1998) Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair

Klinge (1998) Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs

Klinge (1999) Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias

Klinge (2002) Functional and morphological evaluation of a low-weight, monofilament Polypropylene Mesh for Hernia Repair

Klinge (2002) Influence of implantation interval on the long-term biocompatibility of surgical mesh

Klinge (2002) PVDF as a new polymer for the construction of surgical meshes

Klinge (2002) Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model

Klinge (2002) Influence of Mesh Materials on Collagen Deposition in a Rat Model

Klinge (2003) Open Mesh Repair

Klinge (2003) Vypro II® Mesh in Hernia Repair: Impact of Polyglactin on Long-Term Incorporation in Rats

Klinge (2004) - Polypropylene in the intra-abdominal position\_ Influence of pore size

Klinge (2005) Influence of polyglecaprone 25 (Monocryl) supplementation on the biocompatibility of a polypropylene mesh for hernia repair

Klinge (2005) The lightweight and large porous mesh concept for hernia repair

Klinge (2006) Light weight meshes in incisional hernia repair.

Klinge (2007) Experimental Comparison of Monofile Light and Heavy Polypropylene Meshes: Less Weight Does Not Mean Less Biological Response

Klinge (2007) Polymeric meshes induce zonal regulation of matrix metalloproteinase-2 gene expression by macrophages and fibroblasts

Klinge (2008) New polymer for intra-abdominal meshes-PVDF copolymer

Klinge (2010) Large-Pore PDS Mesh Compared to Small-Pore PG Mesh

Klinge (2011) Comparison of Long-Term Biocompability of PVDF and PP Meshes

Klinge (2012) In vivo MRI visualization of mesh shrinkage using surgical implants loaded with superparamagnetic iron oxides

Klinge (2012) Mesh biocompatibility: effects of cellular inflammation and tissue remodelling

Klinge (2012) Modified classification of surgical meshes for hernia repair based on the analyses of 1,000 explanted meshes

Klinge, et al. (2002) Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model (ETH.MESH.02221640 – ETH.MESH.02221646)

Klosterhalfen (2003) Biological response to mesh

Klosterhalfen, et al. (2005) The lightweight and large porous mesh concept for hemia repair (ETH.MESH.02221647 – ETH.MESH.02221661)

Laroche (1995) Polyvinylidene Floride Monofilament Sutures: Can They Be Used Safely for Long-Term Anastomoses in the Thoracic Aorta?

Lucente, et al. Abstract Trans-Vaginal Mesh (TVM): An Innovative Approach to Placing Synthetic Mesh Transvaginally for Surgical Correction of Pelvic Support Defects – Peri-Operative Safety Results

Mary (1998) Comparison of the In Vivo behavior of Polyvinylidene Flouride and Polypropylene Sutures Used in Vascular Surgery

Miller, et al. (2011) Prospective Clinical Assessment of the Transvaginal Mesh Technique for Treatment of Pelvic Organ Prolapse – 5-year Results

Moalli (2012) Uniaxial biomechanical properties of seven different vaginally implanted meshes for pelvic organ prolapse

Moore, et al. (2009) Vaginal Mesh Kits for Pelvic Organ Prolapse, Friend or Foe: A Comprehensive Review

Mouritsen (2007) Vaginal pressure during daily activities before and after vaginal repair

Muhl (2008) New Objective Measurement to Characterize the Porosity of Textile Implants

Nieminen, et al. (2008) Symptom resolution and sexual function after anterior vaginal wall repair with or without polypropylene mesh

Nilsson, et al. (2008) Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence

Ostergard (2011) Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what was known and when it was known

Ozog (2011) Persistence of polypropylene mesh anisotropy after implantation: an experimental study

Ozog (2011) Shrinkage and biomechanical evaluation of lightweight synthetics in a rabbit model for primary fascial repair

Pandit, et al. (2004) Design of surgical meshes – an engineering perspective

Pascual (2008) Early tissue incorporation and collagen deposition in lightweight polypropylene meshes: bioassay in an experimental model of ventral hernia

Rubod & Cosson (2008) Biomechanical properties of vaginal tissue - preliminary results

Scheidbach (2004) - In vivo studies comparing the biocompatibility of various polypropylene meshes and their handling properties during endoscopic total extraperitoneal (TEP) patchplasty

Schug-Paff (2008) A lightweight, partially absorbable mesh (Ultrapro) for endoscopic hernia repair: experimental biocompatibility results obtained with a porcine model

Sivaslioglu, et al. (2008) A randomized comparison of polypropylene mesh surgery with sitespecific surgery in the treatment of cystocele

Sokol 1-Year Objective and Functional Outcomes of a Randomized Clinical Trial of Vaginal Mesh for Prolapse (VAMP) (ETH.MESH.00410458 – ETH.MESH.01823861)

Stanford, et al. (2005) The Use of Mesh in pelvic reconstructive surgery

Tsui, et al. (2005) Complications of synthetic graft materials used in suburethral sling procedures

Usher (1958) Use of marlex mesh in the repair of incisional hernias

Usher (1959) Further observations on the use of marlex mesh – a new technique for the repair of inguinal hernias

Usher (1962) Polypropylene monofilament - a new biologically inert suture for closing contaminated wounds

Williams (1982) Biodegradation of Surgical Polymers

Williams (1992) Mechanisms of Biodegradation of Implantable Polymers

Williams (1994) Biodetrioration/biodegradation of polymeric medical devices In Situ

Winters (2011) Vaginal and Abdominal Reconstructive Surgery for Pelvic Organ Prolapse – Chapter 72 in Wein 10th Ed.

Withhagen, Mariella (2010) Does trocar-guided tension-free vaginal mesh (Prolift) repair provoke prolapse of the unaffected compartments?

Withagen, Mariella (2011) Risk Factors for Exposure, Pain, and Dyspareunia after Tension-Free Vaginal Mesh Procedure

Woodruff (2008) Histologic Comparison of Pubovagianl Sling Graft Materials A comparative Study

Gynecare Gynemesh PS Nonabsorbable Prolene Soft Mesh IFU

Gynecare Prolift IFU dated 2004 (Exh. 10) ETH-00295 - ETH-00300

Gynecare Prolift IFU dated 2009 (Exh. 13) ETH-10977 - ETH-10983

Anatomic Overview of Prolift Anterior and Posterior Procedure

Gynecare Prolift Pelvic Floor Repair Systems Procedure DVD

TVT IFUs

Gynemesh PS A New Mesh for Pelvic Floor Repair - Early Clinical Experience

Gynecare Prolift Pelvic Floor Repair System Surgical Technique Guide

Ethicon Memo to R. Roussesau from Thomas Barbolt dated 12/2/99 re: Biocompatibility Risk Assessment for Soft PROLENE Mesh

Ethicon Report, PSE Accession No. 00-272, Project No. 48010 Design Verification: Evaluation of Visibility, Hardness, Resistance to Cannula Damage, and Fixation Properties of Soft Prolene Mesh ETH.MESH00220901 – 0911

Ethicon March 5, 2001 Memo to Prolene Soft Mesh Team re: Prolene Soft Mesh Validation Completion Report for Pre and Intra-Operative Usage from Mark Mooney Ethicon Final Report PSE Accession No. 00-0035 An Exploratory 91-day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats (PSE ACC. NO. 00-0035) dated 7/11/01

Ethicon December 2, 2001 Memo to Maggie D'Aversa from David Stoloff re: Gynemesh Prolene Soft Mesh – Preclinical Functionality Testing Strategy ETH.MESH.00220875 – 0877

Ethicon Final Report PSE Accession No. 01-0321, Project No. 48010 A 28-day Tissue Reaction Study of Prolene Polypropylene Mesh and Autoclaved Prolene Polypropylene Mesh Implanted Intramuscularly and Subcutaneously in Rats dated 5/23/02 – ETH.MESH02216602 – 6611

Ethicon Final Report PSE Accession No. 02-0079 14-day Adhesion Prevention Study of Interceed Fabric, PDS or POE VI-Based Films on Prolene-Soft, Pronova, or Vypro Mesh, and Competitive products in the Rabbit Sidewall Model with Peritoneal Defects dated 10/28/02 – ETH.MESH.021338843 – 3861

Ethicon Report PSE Accession No. 02-0579 Project No. 48010, Histological Evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model dated 3/5/03. First page only numbered 0300241

Ethicon Report dated 1/19/05 Biocompatability Risk Assessment for Gynecare PROLIFT Total Pelvic Floor Repair System ETH.MESH.01310817 - ETH.MESH.01310829

Ethicon Completion Report: BE-2004-1606 Design Verification for the Gynecare Prolift Kit – Interface, Human Factors, Function, and Clinical Requirements dated 1/27/05 ETH.MESH.01310776 – 0812

Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse dated 6/27/06 — Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse ETH.MESH.00012009 - ETH.MESH.00012089

Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse dated 6/28/06 – Clinical assessment of the TVM technique for treatment of genital prolapse. Final report of 12-month evaluation. ETH.MESH.00012090 - ETH.MESH.00012163

Final Report PSE Study No. 08-0311; Project No 67624 – A 6-month Pilot Study to Evaluate Matrix Materials in a Rabbit Subcutaneous Implantation Model dated 2/24/12

Chart comparing Ethicon, AMS and Bard's products by Characteristic, Area Weight, Largest Pore Size (n=5), Porosity, Bending Stiffness-Body, and Burst Pressure – Body

Ethicon Performance Evaluation Technical Report Assessment of Competitor Pelvic Floor Repair Meshes, Version 1 Study Number CPC-2006-0552 ETH.MESH.02181321 – 1337

International Urogynecological Association: The Usage of Grafts in Pelvic Reconstructive Surgery Symposium 2005

Uwe Klinge Expert Report

Thomas Muhl Expert Report

Thomas Mang Expert Report

**Donald Kreutzer Expert Report** 

William Welch Expert Report

**Edmond Provder Expert Report on Gross** 

Michael Margolis Expert Report on Gross

Ronni Seltzer Expert Report on Gross

Claire Serrato Expert Report on Gross

Ann Weber Expert Report on Gross

William Welch Expert Report on Gross

October, 2012

# **CURRICULUM VITAE**

Name: Stephen Michael Factor, M.D.

Date of Birth: October 28, 1942

Place of Birth: New York, NY

Nationality: USA

Present Title: Professor of Pathology and Professor of Medicine (Cardiology) with tenure

Board Certification: Anatomic and Clinical Pathology, 1975

Licensure: New York State, #108706, 1971

New York State Licensed Laboratory Director

# **EDUCATION:**

Queens College of the City University of New York, NY, B.A., 1964 Albert Einstein College of Medicine, Bronx, NY, M.D., 1968

# **HONORS:**

Albert Einstein Colle	ege of N	/ledicine,	Bronx, NY:	
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Alpha Omega Alpha Honor Society (election Junior year)	1967
Abraham and Joseph Spector Fellowship in Pathology	1978-present
Leo M. Davidoff Society for excellence in teaching	1988
Tenured appointment	1989
First recipient, Harry Eagle Award for Outstanding Basic Science	
Teaching	1995
Distinguished Alumnus (selected from over 8,000 graduates)	1998

#### National:

Fellow, American College of Cardiology	1983
Fellow, New York Cardiological Society	1985
Fellow, College of American Pathologists	1986
President, Society for Cardiovascular Pathology	1988-1989
Editor-in-Chief and Founding Editor,	
CARDIOVASCULAR PATHOLOGY	1991-2001
Fellow, Wildlife Conservation Society	1999-2002

<b>CLINICAL AN</b>	ID ADMINISTF	ATIVE RESP	ONSIBILITIES:

Jacobi Medical Center (formerly Bronx Municipal Hospital Center), Bronx, NY

Director, Department of Anatomic Pathology

1985-1997

Member, Executive Committee, Medical Board

Attending Pathologist

Chairman, Department of Pathology

1997-

Chairman, Search Committee for Chairman,

Department of Surgery

2010-2011

Member, Executive Committee, New York Medical Associates (NYMA)

#### PROFESSIONAL EXPERIENCE:

University of Michigan Hospitals, Ann Arbor, MI

Department of Surgery

Intern

1968-1969

Resident

1969-1970

Albert Einstein College of Medicine and Affiliated Hospitals,

Bronx Municipal Hospital Center and Weiler Hospital of the Albert Einstein College of Medicine, Bronx, NY

Department of Pathology

Resident, Anatomic and Clinical Pathology

1970-1971

United States Army Medical Corps

1971-1973

Captain (1971), and Major (1972-1973)

Martin Army Hospital, Fort Benning, GA

Chief, Anatomic Pathology Service

1972-1973

Homer Cobb Memorial Hospital, Phenix City, AL

Visiting Pathologist

1972-1973

Albert Einstein College of Medicine and Affiliated Hospitals,

Bronx Municipal Hospital Center and Weiler Hospital of the Albert Einstein College of Medicine, Bronx, NY

Department of Pathology

Resident, Anatomic and Clinical Pathology 1973-1975 Chief Resident 1974-1975

Albert Einstein College of Medicine, Bronx, NY

Department of Pathology

Assistant Instructor 1974-1975
Assistant Professor 1975-1980
Associate Professor 1980-1985
Professor 1985
Tenured appointment 1989
Vice Chairman for Anatomic Pathology 1993-1995

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Department of Medicine	
Associate Professor, Division of Cardiology	1987
Professor, Division of Cardiology	1989
Tenured appointment	1989
Torrai od apportation	
MEDICAL SCHOOL SERVICE:	
Albert Einstein College of Medicine, Bronx, NY:	
Student-Faculty Senate, elected Senator	1976-1981
olddon I ddany Condio, Cressia Condi	1982-1986
	1988-1990
	1990-1992
	1993-1995
Student Promotions Committee	1978-1998
Dean's Advisory Committee on the Electron Microscopy Center	1980-1981
Space Committee	1983-1984
Committee on Appointments and Promotions, Professors	1985-1990
Co-chairman	1988-1989
Chairman	1989-1990
Search Committee, Chairman Physiology and Biophysics	1988-1991
Search Committee, Chairman Cardiothoracic Surgery	1988-1990
Chairman, Subcommittee for Institutional Self-Study,	
Clinical Departments, LCME	1990-1991
Educational Policy and Planning Committee	1991-1995
Co-chairman	1992-1995
Tenure Committee	1996-1999
Division of Education, Co-chairman	1996-2000
Search Committee, Chairman Internal Medicine	1998-1999
Division of Education, Executive Committee	2000-present
Medical School Student Admission Committee	1977-present
Co-chairman	1987-2010
Basic Science Course Leaders Committee	2003-present
Scientific Foundations of Medicine Committee	2003-present
WITHIN THE DEPARTMENT OF PATHOLOGY:	
Chairman, Resident Affairs Committee	1976-1983
Chairman, Resident Selection Committee	1983-1985
Course Leader & Primary Lecturer in Cardiovascular Pathology	
and Medicine	1976-present
Senior Faculty Advisory Committee	1986-1993
Steering Committee	1993-1995

# INVITED LECTURES & PROGRAM CHAIRMANSHIPS (SELECTED): 1983-present

Blenheim Conference on Ischemic Heart Disease Blenheim Palace, England Invited participant-1983

Chinese Academy of Medical Sciences
Peoples Republic of China

Invited lecturer, 10 Medical Schools-1985

Third Antwerp-La Jolla-Kyoto Research Conference on Cardiac Function Kyoto, Japan Invited participant, and Session Chairman-June, 1987

Fourth World Congress for Microcirculation
Tokyo and Osaka, Japan
Invited participant and Session Chairman-July-August, 1987

International Society for Heart Research
European Division, Budapest, Hungary
Invited participant and Session Chairman-September, 1987

Inflammatory Heart Disease Snowmass, CO Invited participant-July, 1988

International Society for Heart Research European Division, Oxford, England Session Chairman-September, 1988

American Heart Association, 61st Annual Scientific Session Washington, D.C.
Session Co-chairman-November, 1988

NIH Conference on Modeling in Biomedical Research Invited speaker-May, 1989

International Symposium on the Diabetic Heart
Tokyo, Japan
Invited speaker and Session Chairman-October, 1989

American Heart Association, 62nd Annual Scientific Session New Orleans, LA Session Co-Chairman-November, 1989

Conference on Diabetes

Montpelier, France Invited speaker-July, 1990

University of Pennsylvania, Department of Cardiothoracic Surgery Philadelphia, PA Invited speaker-August, 1990

Endocrines and the Heart
Brussels, Belgium
Invited speaker-October, 1990

Frontiers in Heart Failure
Whistler, British Columbia
Invited speaker-February, 1991

Society for Cardiovascular Pathology Chicago, IL Invited speaker-March, 1991

Chairman, Mini-Symposium on Cardiovascular Pathology, FASEB Atlanta, GA-April, 1991

Second International Symposium on Myocarditis Airlie, VA Invited speaker-May, 1991

International Symposium on Idiopathic Dilated Cardiomyopathy Baden-Baden, Germany Invited speaker-January, 1992

Cellular Abnormalities Associated with Cardiomyopathies in Animals Tokyo, Japan Invited Speaker Member, International Advisory Committee-May, 1992

Symposium on Ischemic Heart Disease International Academy of Pathology Madrid, Spain Invited Speaker-October, 1992

Second International Cardiovascular Pathology Course University of Toronto Invited Speaker-June, 1992

Third International Symposium on the Pig Model for Biomedical Research (Hypertrophic Cardiomyopathy)
Taipei, Taiwan
Invited Speaker-November, 1992

American Physiology Society (FASEB) Symposium Speaker-April, 1993

International Society for Heart Research (ISHR)
Symposium Speaker-June, 1993

National Taiwan University, Taiwan Kaohshiung Medical College, Taiwan Chinese University of Hong Kong Invited Lecturer-October, 1993

XIIth World Congress of Cardiology Berlin, Germany Invited Speaker-September, 1994

XXth International Congress of the International Academy of Pathology Hong Kong Symposium Chairman and Organizer-October, 1994

Congress of the Italian Society of Cardiology
Rome, Italy
Invited Lecturer and Honoree of the Cardiovascular
Pathology Group-December, 1994

American Society of Investigative Pathology
Atlanta, GA
Symposium Co-chairman and Lecture-April, 1995

Chagas' Heart Disease Symposium Milan, Italy Invited Speaker-June, 1995

Symposium on Hypertensions and Diabetes Mellitus Budapest, Hungary Invited Speaker-July, 1995

Dedication of Cardiovascular Center, Pig Research Institute of Taiwan Maioli, Taiwan Keynote Speaker-October, 1995 Keystone Symposium, Immunologic Aspects of Cardiovascular Disease

1984

Invited Speaker-January, 1997

International Society for Heart Research Symposium Co-chairman Vancouver-July, 1997

US & Canadian Academy of Pathology Cardiovascular Pathology Symposium Boston, MA Invited Speaker-March, 1998

Oklahoma University Health Sciences Center Oklahoma City, OK Invited Speaker-November, 1998

NIH Special Study Section, Ad Hoc Member

Heart Failure Society of America San Francisco, CA Invited Speaker-September, 1999

Curriculum Committee: Diabetes for the Cardiovascular Specialist Atlanta, GA Invited Speaker and Participant, November, 1999

US & Canadian Academy of Pathology Cardiac Case Conference Chicago, IL Invited Speaker, February, 2002

National Panel on Definition and Diagnosis of Myocarditis

# OTHER:

1984 Invited participant Consultant and Panel Pathologist 1986-1994 Multicenter Myocarditis Treatment Trial Site Visitor, Massachusetts General Hospital 1986-1987 Ischemia SCOR Grant NIH (NHLBI), Cardiovascular A Study Section Ad Hoc Member 1990 NIH Parent Review Committee, Atherosclerosis SCOR 1991 (including chairing site visit) NIH (NHLBI) Special Study Section 1992 Cardiovascular Disease in Blacks and Women

NIH (NHLBI) Reverse site visit member Ischemia SCOR	1994
NIH (NHLBI) Ad Hoc Member, Cardiovascular B Study Section	1996
NIH (NHBLI) Member, SCOR Study Section	1996
American Heart Association, Committee on Scientific Sessions Program, Circulation Council	1996
NIH (NHLBI) Special Emphasis Panel Genesis of Cardiomyopathy with HIV Infection and Alcohol Abuse	1999
Mortality and Morbidity Panel, REMATCH Trial- Left Ventricular Assist D (LVAD), Columbia-Presbyterian	evice 2000-

# **PROFESSIONAL SOCIETIES:**

Federation of American Societies for Experimental Biology (AAP)

Fellow, American College of Cardiology

Fellow, College of American Pathologists

New York Pathological Society - Trustee

1990-1994

New York Pathologists Club

New York and American Heart Association

American Heart Association Council on Basic Science

Fellow, The New York Cardiological Society

International Academy of Pathology, North American Division

International Society for Heart Research, American Division

International Association for Cardiac Biological Implants Society for Cardiovascular Pathology

Society for Cardiovascular Pathology (Founding Member)

Steering Committee and Chairman of Governance Committee	1986-198 <i>7</i>
Vice President and President-elect	1987-1988
President	1988-1989
Chairman, Publications Committee	1989-1990
Immediate Past President and Member of Executive Board	1989-1991
Member of Executive Board, ex officio	1991-present
Association of Directors of Anatomic and Surgical Pathology	1993-2004

## **EDITORIAL ACTIVITIES:**

1. Editorial Boards

The Journal of the American College of Cardiology 1986-1991
The American Journal of Cardiovascular Pathology 1986-1996
The American Journal of Pathology 2008-

2. Editor-in-Chief, Cardiovascular Pathology

1991-1996 1997-2001

3. Ad Hoc Manuscript Reviewer for:

American Journal of Pathology

Circulation

Circulation Research

American Journal of Physiology

Diabetes

Microvascular Research

Journal of The American College of Cardiology

Basic Research in Cardiology

American Journal of Cardiology

Journal of Molecular and Cellular Cardiology

Laboratory Investigation

Research Communications in Chemical Pathology and Pharmacology

New England Journal of Medicine

Life Sciences Journal

Journal of Clinical Investigation

#### OTHER REVIEWS:

External Reviewer, grant applications to:

Heart and Stroke Foundation of Canada

British Columbia Health Care Research Foundation

American Heart Association (abstracts, Scientific Session)

American College of Cardiology (abstracts, Scientific Session)

Academic Consultant in Pathology to Columbia University Press,

Publisher of The Columbia Encyclopedia 1990-1993

# **MAJOR RESEARCH INTERESTS:**

Cardiomyopathy (clinical and animal models)

Diabetic and hypertensive heart disease

Myocardial ischemia and infarction (experimental and clinical)

Cardiac microcirculation

Myocardial connective tissue matrix

Atherosclerosis

Pulmonary circulation

## **GRANT SUPPORT:**

NIH #HL-20426 MYOCARDIAL FUNCTION IN DIABETES MELLITUS

PI: EH Sonnenblick

9/1/81-3/31/84

SM Factor: 12% effort

NIH #HL-23171 CORONARY CIRCULATION IN MYOCARDIAL ISCHEMIA

PI: ES Kirk 7/1/78-6/30/84

SM Factor: 20% effort

NIH #HL-18824 MECHANISMS OF HEART FAILURE IN THE MYOPATHIC HAMSTER

PI: EH Sonnenblick 4/1/79-3/31/84

SM Factor: 7% effort

7/1/84-6/30/87 Total amount of grant: \$1,104,002

SM Factor: 25% effort

NIH #HL-29812 MICROVASCULAR DETERMINANTS OF FOCAL MYOCARDIAL NECROSIS

PI: SM Factor

7/1/83-6/30/86 Total amount of grant: \$226,099

SM Factor: 20% of effort

NIH #HL-33240 HEART FAILURE IN HYPERTENSIVE DIABETIC ANIMALS

PI: FS Fein

2/1/84-11/30/87 Total amount of grant: \$372,856

SM Factor: 5% of effort

NIH #HL-35882 PATHOGENESIS OF CARDIOMYOPATHY

PI: M Wittner 12/1/85-11/30/88

SM Factor: 5% of effort

NIH #HL-23171 CORONARY CIRCULATION IN MYOCARDIAL ISCHEMIA

PI: R Forman

7/1/84-6/30/87 Total amount of grant: \$382,959

SM Factor: 10% of effort

NIH #HL-34744-01 IMMUNOSUPPRESSIVE THERAPY FOR BIOPSY-PROVEN MYOCARDITIS

PI: JW Mason

7/1/86-6/30/89 Total amount of grant: \$4,718,460 (grant extended 1990) Consultant

SM Factor: 2 meetings yearly

NIH #HL-37412-01 PROGRAM PROJECT: MECHANISMS OF MYOCARDIAL DYSFUNCTION AND FAILURE

PI: EH Sonnenblick

9/30/88-9/29/93 Total amount of grant: \$4,845,894 SM Factor, PI Project #3, 9/30/91-9/29/92 \$130,697

NIH #HL-27219-11 THE CORONARY CIRCULATION AND MYOCARDIAL ISCHEMIA

PI: C Eng

7/1/88-6/30/91 Total amount of grant: \$439,714

SM Factor: 10% of effort

7/1/93-6/30/94 (Subcontract: Total Direct Amount \$19,948)

NIH # HL-07071 (Training Grant) CARDIOVASCULAR PHYSIOLOGY AND

**PATHOPHYSIOLOGY** 

PI: RS Aronson

7/1/85-6/30/90 Annual Direct Costs: \$99,614

NY Heart Association, MEDICAL STUDENT RESEARCH FELLOWSHIP

PI: SM Factor 7/92-6/95

NIH #A-3312-01 GENETIC BASIS OF THE PATHOLOGIC ANTI-MYOSIN RESPONSE

PI: B Diamond

7/1/94-6/30-98 Total amount of grant: \$1,017,990

SM Factor: 10% of effort

NY Heart Association, MEDICAL STUDENT RESEARCH FELLOWSHIP

PI: SM Factor 7/94-6/97

NIH #1R01AR 43018, GENETIC BASIS OF THE PATHOLOGIC ANTI-MYOSIN RESPONSE

PI: B Diamond

6/23/95-4/30/99 Annual Direct Costs: \$12,500

SM Factor: 2% of effort

#### PERSONAL:

Married to the former Sandra Helene Basner, M.S., J.D.

Children: Jason Robert, J.D.

Rachel Elizabeth, M.D.

Home Address: 19 Dan Beard Lane West Redding, CT 06896

# **PUBLICATIONS:**

- 1. Hall JW, Factor SM, Cerny JC: Traumatic renal artery aneurysm in a solitary kidney. J Urol 107:17-20, 1972
- 2. Factor SM: Papillary adenocarcinoma of the endometrium with psammoma bodies. Arch Pathol 98:201-205, 1974
- 3. Halpern GN, Kalies DW, Factor SM, Wein AJ: Malacoplakia causing bilateral ureteropelvic junction obstruction. Urology 3:628-631, 1974
- 4. Factor SM: Granulomatous pneumonitis: a result of intrapleural instillation of atabrine and talcum powder. Arch Pathol 100:499-502, 1975
- 5. Friedman A, Factor SM: Correlation conferences in radiology and pathology: calcified upper abdominal mass. NY State J Med 76:1320-1323, 1976
- 6. Lutzker L, Factor SM: The effects of water soluble contrast agents on colon mucosa. Radiology 118:545-548, 1976
- 7. Factor SM, Turi G, Biempica L: Primary cardiac neurilemmoma. Cancer 37:883-890, 1976
- Factor SM: Intramyocardial small vessel disease in chronic alcoholism. Am Heart J 92:561-575, 1976
- 9. Coltoff-Schiller B, Goldfischer S, Wolinsky H, Factor SM: Lipid accumulation in human aortic smooth muscle lysosomes. Am J Pathol 83:39-44, 1976
- 10. Factor SM, Biempica L, Ratner I, Ahuja KK, Biempica S: Carcinoma of the breast with multinucleated reactive stromal giant cells. Virch Arch Pathol A 374:1-12, 1977
- 11. Factor SM, Biempica L, Goldfischer S: Intralysosomal accumulation of lipid in the atherosclerosis of chronic organ transplantation. Arch Pathol Lab Med 101:474-477, 1977
- 12. Puri S, Farmer P, Factor SM: Sclerosing mediastinitis due to aspergillus. NY State J Med 77:774-777, 1977
- 13. Pasternak BM, Rosen S, Sanson L, Factor SM: Progressive occlusive thromboarteriopathy. Angiology 29:705-712, 1978
- 14. Factor SM, Biempica L, Winn RM: The histiocytic origin of the multinucleated cells in myeloma kidney. Hum Pathol 9:114-120, 1978

- 15. Factor SM: Endocardial fibroelastosis: myocardial and vascular alterations associated with viral-like nuclear particles. Am Heart J 96:791-801, 1978
- 16. Factor SM, Sonnenblick EH, Kirk ES: Histological border zone of acute myocardial infarction: islands or peninsulas? Am J Pathol 92:111-124, 1978
- 17. Factor SM, Goldfischer S, Biempica L: Coronary intimal sclerosis in Morquio's syndrome. Virch Arch Pathol A 379:1-10, 1978
- Strobeck JE, Factor SM, Bhan A, Sole M, Liew CC, Fein F, Sonnenblick EH: Hereditary and acquired cardiomyopathies in experimental animals: mechanical, biochemical, and structural features. Ann NY Acad Sci 317:59-88, 1979
- 19. Frishman W, Factor SM, Jordan A, Hellman C, Elkayam U, Lejemtel T, Strom J, Unschuld H, Becker R: Right atrial myxoma: unusual clinical presentation and atypical glandular histology. Circulation 59:1070-1075, 1979
- 20. Factor SM, Frishman W: Sudden death in a narcotic addict four months following aortic valve replacement. (CPC). Am Heart J 98:233-242, 1979
- 21. Koss J, Factor SM: Diabetes mellitus, malabsorption, and congestive heart failure in a middle-aged man. A case of thesaurosclerosis. (CPC). Am Heart J 98:77-787, 1979
- Herskowitz A, Factor SM: Duplication of the mitral valve, with a discussion of the embryogenesis of AV valve duplication. NY State J Med 70:260-263, 1979
- Lejemtel T, Factor SM, Koenigsberg M, O'Reilly M, Frater R, Sonnenblick EH: Mural vegetations at the site of endocardial trauma in bacterial endocarditis complicating idiopathic subaortic stenosis. Am J Cardiol 44:569-574, 1979
- 24. Okun EM, Factor SM, Kirk ES: End-capillary loops in the heart: An explanation for discrete myocardial infarctions without border zones. Science 206:565-567, 1979
- 25. Ongseng F, Chervu LR, Kogan SJ, Factor SM, Levitt SB, Blaufox MD: Static testicular imaging utilizing 201 Tl. Invest Urol 16:451-452, 1979
- 26. Factor SM, Reichel J: Primary pulmonary hypertension. (CPC). Am Heart J 99:789-798, 1980
- 27. Herskowitz A, Cho S, Factor SM: Syphilitic coronary arteritis. NY State J Med 80:971-974, 1980
- 28. Factor SM, Minase T, Sonnenblick EH: Clinical and morphological features of human hypertensive-diabetic cardiomyopathy. Am Heart J 99:446-458, 1980

- 29. Factor SM, Okun EM, Minase T: Capillary microaneurysms in the human diabetic heart. N Eng J Med 302:384-388, 1980
- 30. Factor SM: Microvascular injection of the human heart. Med Radiogr Photogr 56:cover (and accompanying article), 1980
- 31. Factor SM, Okun EM, Kirk ES: The histological lateral border of acute canine myocardial infarction: a function of the microcirculation. Circ Res 48:640-649, 1981
- 32. Tanowitz H, Davies P, Factor SM, Minase T, Herskowitz A, Wittner M: Comparison of choline acetyl transferase activity and morphology in susceptible and resistant inbred mice infected with the Brazil strain of T. cruzi. Exp Parasitol 51:269-278, 1981
- 33. Factor SM, Rubin K, Frishman W: Adult respiratory distress syndrome one month following myocardial infarction. NY State J Med 81:226-234, 1981
- 34. Factor SM, Bhan R, Minase T, Wolinsky H, Sonnenblick EH: Hypertensive-diabetic cardiomyopathy in the rat: an experimental model of human disease. Am J Pathol 102:219-228, 1981
- 35. Factor SM: Intramural pathology in the diabetic heart: interstitial and microvascular alterations. Mt Sinai J Med 49:208-214, 1981
- Koenigsberg M, Factor SM, Cho S, Herskowitz A, Nitowsky H, Morecki R: Fetal Marfan's syndrome: prenatal ultrasound diagnosis with pathological confirmation of skeletal and aortic lesions. Prenat Diag 1:241-247, 1982
- 37. Factor SM, Kirk ES: Microcirculatory determinants of infarct dimensions. In, MICRO-CIRCULATION OF THE HEART, (eds. H Tillmanns, W Kubler, H Zebe). Springer-Verlag, Berlin, 1982, pp 141-148
- 38. Sonnenblick EH, Factor SM, Strobeck JE, Capasso J, Fein F: The pathophysiology of heart failure: the primary role of microvascular hyper-reactivity and spasm in the development of congestive cardiomyopathies. In, CONGESTIVE HEART FAILURE: CURRENT RESEARCH AND CLINICAL APPLICATIONS, (eds. E Braunwald, MB Mock, J. Watson). Grune & Stratton, NY, 1982, pp 323-327
- 39. Factor SM, Minase T, Cho S, Dominitz R, Sonnenblick EH: Microvascular spasm in the cardiomyopathic Syrian hamster: a preventable cause of focal myocardial necrosis. Circulation 66:342-354, 1982
- Factor SM, Cho S, Sonnenblick EH: Diabetic heart disease: microvascular abnormalities in clinical and experimental cardiomyopathy. In, ADVANCES IN PATHOLOGY, (ed. E Levy). Pergamon Press, Oxford, 1982, pp 323-327

- Factor SM, Sonnenblick EH: Hypothesis: is congestive cardiomyopathy secondary to a hyper-reactive myocardial microcirculation (microvascular spasm)? Am J Cardiol 50:1149-1152, 1982
- 42. Factor SM, Cho S, Sternlieb I, Scheinberg IH, Goldfischer S: The cardiomyopathy of Wilson's disease: myocardial alterations in nine cases. Virch Arch Pathol A 397:301-311, 1982
- 43. Gabbay S, Factor SM, Strom J, Becker R, Frater RWM: Sudden death due to cuspal dehiscence of the lonescu-Shiley valve in the mitral position. J Thorac Cardiovasc Surg 84:313-314, 1982
- 44. Factor SM, Okun EM, Minase T, Kirk ES: The microcirculation of the human heart: end-capillary loops with discrete perfusion fields. Circulation 66:1241-1248, 1982
- 45. Matos MI, Factor SM: Hemoptysis and abdominal pain in a 74 year old man. (CPC). Einstein Quart J Biol Med 1:95-102, 1982
- Forman R, Cho S, Factor SM, Kirk ES: Acute myocardial infarct extension into a previously preserved subendocardial region at risk in dogs and patients. Circulation 67:117-124, 1983
- 47. Frater RWM, Gabbay S, Shore D, Factor S, Strom J: Reproducible replacement of elongated or ruptured mitral valve chordae. Ann Thorac Surg 35:14-28, 1983
- 48. Factor SM, Minase T, Bhan R, Wolinsky H, Sonnenblick EH: Hypertensive-diabetic cardiomyopathy in the rat: ultrastructural features. Virch Arch Pathol A 398:305-317, 1983
- 49. Sonnenblick EH, Strobeck J, Capasso J, Factor SM: Ventricular Hypertrophy: Models and Methods. In, PERSPECTIVES IN CARDIOVASCULAR RESEARCH, (eds. RC Tarazi, JB Dunar). Raven Press, NY, 1983, pp 13-20
- 50. Hyman A, Podolsky A, Factor SM: Focal adrenal necrosis and fibrosis in a general autopsy population. New York State J Med 83:829-834, 1983
- 51. Factor SM, Sonnenblick EH: Microvascular spasm as a cause of cardiomyopathies. Cardiovasc Rev Rep 4:1177-1182, 1983
- 52. Pick P, Jean E, Horoupian D, Factor S: Xanthogranuloma of the dura in systemic Weber-Christian disease. Neurology 33:1067- 1070, 1983
- Fein FS, Factor SM, Cho S, Miller-Green B, Carroll D, Sonnenblick EH: Catecholamine induced myocardial necrosis in experimental diabetes mellitus. Arch Pathol Lab Med 107:480-483, 1983

- Robinson TF, Cohen-Gould L, Factor SM: Skeletal framework of mammalian heart muscle. Arrangement of inter- and pericellular connective tissue structures. Lab Invest 49:482-498, 1983
- 55. Sonnenblick EH, Factor SM, Lejemtel TH: The rationale for inotropic therapy in heart failure. Cardiovasc Rev Rep 4:910- 925, 1983
- Strom JA, Gabbay S, Factor SM, Frishman WH, Frater RWM: Prospective diagnosis of a dehisced cusp of an lonescu-Shiley pericardial xenograft valve by non-invasive methods. Med Ultrasound 7:127-131, 1983
- 57. Katz DA, Ben-Ezra J, Factor SM, Horoupian DS, Goldfischer S: Fatal pulmonary and cerebral fat embolism in systemic lupus erythematosus. JAMA 250:2666-2669, 1983
- 58. Strain JE, Grose RM, Factor SM, Fisher JD: Endomyocardial biopsy results in patients with clinically normal hearts and spontaneous ventricular tachycardia. Circulation 68:1171-1181, 1983
- 59. Eng C, Cho S, Factor SM, Sonnenblick EH, Kirk ES: Myocardial micronecrosis produced by microsphere embolization. Role of an alpha adrenergic tonic influence of the coronary microcirculation. Circ Res 54:74-82, 1984
- 60. Rose AG, Halper J, Factor SM: Pulmonary arteriopathy in Takayasu's disease. Arch Pathol Lab Med 108:664-648, 1984
- 61. Factor SM, Minase T, Cho S, Fein F, Capasso JM, Sonnenblick EH: Coronary microvascular abnormalities in the hypertensive-diabetic rat. A cause of cardiomyopathy? Am J Pathol 116:9-20, 1984
- 62. Halper J, Factor SM: Coronary lesions in neurofibromatosis associated with presumptive coronary spasm and fatal myocardial infarction. Am Heart J 108:420-422, 1984
- 63. Fein FS, Capasso JM, Aronson RS, Cho S, Nordin C, Miller-Green B, Sonnenblick EH, Factor SM: Combined renovascular hypertension and diabetes in rats: a new preparation of congestive cardiomyopathy. Circulation 70:318-330, 1984
- Gabbay S, Bortolotti U, Cipolletti G, Wasserman F, Frater RWM, Factor SM: The Meadox unicusp pericardial bioprosthetic heart valve: new concept. Ann Thorac Surg 37:448-456, 1984
- 65. Gabbay S, Bortolotti U, Factor S, Shore DF, Frater RWM: Calcification of implanted xenograft pericardium influence of site and function. J Thorac Cardiovasc Surg 87:782-787, 1984

- 66. Gabbay S, Bortolotti U, Wasserman F, Factor S, Strom J, Frater RWM: Fatigue-induced failure of the lonescu-Shiley pericardial xenograft in the mitral position: in vivo and in vitro correlation and a proposed classification. J Thorac Cardiovasc Surg 87:836-844, 1984
- 67. Gabbay S, Bortolotti U, Wasserman F, Tindel N, Factor SM, Frater RWM: Long-term follow-up of the Ionescu-Shiley mitral pericardial xenograft. J Thorac Cardiovasc Surg 88:758-763, 1984
- 68. Sonnenblick EH, Factor SM: Heterogeneous transmural blood flow and microvascular spasm as causes of heart failure in ischemic heart disease and cardiomyopathies. In, REGULATION OF CARDIAC FUNCTION, (eds. H Abe, Y Ito, M Tada, LH Opie). Japan Scientific Society Press, Tokyo, 1984, pp 191-196
- 69. Gabbay S, Bortolotti U, Wasserman F, Factor SM: Haemodynamics and durability of mitral bioprostheses-an in vitro study. Eur Heart J 5 (suppl D):65-71, 1984
- 70. Kirk ES, Factor S, Sonnenblick EH: Newer concepts in the pathophysiology of ischemic heart disease. G Ital Cardiol 4:881- 891, 1984
- 71. Robinson TF, Cohen-Gould L, Remily RM, Capasso JM, Factor SM: Extra-cellular structures in heart muscle. Adv Myocardiol 5:243-255, 1985
- 72. Sonnenblick EH, Factor SM: Microvascular spasm as a cause of cardiomyopathies and the calcium blocking agent (verapamil) as potential primary therapy. Am J Cardiol 55:179-184, 1985
- 73. Forman R, Cho S, Factor SM, Kirk ES: Lateral border zone: quantitation of lateral extension of subendocardial infarction in the dog. J Am Coll Cardiol 5:1125-1131, 1985
- 74. Factor SM, Cho S, Wittner M, Tanowitz H: Abnormalities of the coronary microcirculation in acute murine Chagas' disease. Am J Trop Med Hyg 34:246-253, 1985
- 75. Sole MJ, Factor SM: Hamster cardiomyopathy: A genetically transmitted sympathetic dystrophy. In, PATHOGENESIS OF STRESS- INDUCED HEART DISEASE, (eds. RE Beamish, V Panagia, NS Dhalla). Martinus Nijhoff Publishing, Boston, 1985, pp 34-43
- 76. Jones JG, Factor SM: Familial congestive cardiomyopathy with nemaline rods in heart and skeletal muscle. Virch Arch Pathol A 408:307-312, 1985
- 77. Factor SM, Cho S: Smooth muscle contraction bands in the media of coronary arteries: a post-mortem marker of ante-mortem spasm? J Am Coll Cardiol 6:1329-1337, 1985
- 78. Brosnan CF, Goldmuntz EA, Cammer W, Factor SM, Bloom BR, Norton WT: Prazosin, an alpha-l-adrenergic receptor antagonist, suppresses experimental autoimmune encephalomyelitis in the Lewis rat. Proc Natl Acad Sci 82:5915-5919, 1985

- 79. Factor SM, Kirk ES: Pathophysiology of myocardial ischemia. In, THE HEART, (ed. JW Hurst). 6th edition, Chap 44, McGraw Hill, NY, 1985, pp. 856-881
- 80. Factor SM, Sonnenblick EH: The pathogenesis of clinical and experimental congestive cardiomyopathies: Recent concepts. Prog Cardiovasc Dis 27:395-420, 1985
- 81. Factor SM: The diagnostic usefulness of right ventricular endomyocardial biopsy. Heart Failure 2:56-63, 1986
- 82. Mancini DM, LeJemtel TH, Factor S, Sonnenblick EH: The central and peripheral components of heart failure. Am J Med 80:2-13, 1986
- 83. Gelman KM, Ben-Ezra JM, Steinschneider M, Keefe DL, Dutcher J, Factor SM: Primary cardiac lymphoma. Am Heart J 111:808-811, 1986
- 84. Bier A, Jones J, Lazar E, Factor S, Keefe D: Endocarditis of a tricuspid prosthesis causing valvular stenosis and shunting through a patent foramen ovale. Chest 90:293-295, 1986
- Robinson TF, Factor SM, Sonnenblick EH: The heart as a dynamic suction pump. A reappraisal of the classic Frank-Starling law of the heart. Sci Am 254:84-91, 1986
- 86. Bortolotti U, Gallo JI, Gabbay S, Factor SM, Sisto D, Frater RWM: Replacement of mitral valve chordae with autologous pericardium in dogs. Thorac Cardiovasc Surg 32:15-17, 1986
- 87. Vetter HO, Burack JH, Factor SM, Macaluso MA, Frater RWM: Replacement of chordae tendineae of the mitral valve using the new expanded PFTE-suture in sheep. In, BIOLOGICAL AND BIOPROSTHETIC VALVES, (eds. R Bodnar, M Yacoub). York Medical Books, NY, 1986, pp 772-784
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